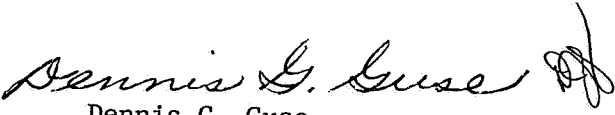


TECHNICAL SUPPORT SECTION EFFICACY REVIEW - I

Disinfectants Branch

IN 04-23-80 OUT 06-12-80

Reviewed By Dennis G. Guse  Date 06-12-80

EPA Reg. No. or File Symbol 10466-EI

EPA Petition or EUP No. None

Date Division Received 03-06-80

Type Product Industrial preservative

Data Accession No(s) None

Product Manager 31 (Lee)

Product Name Steri-Septic DM-50

Company Name Thomson Research Associates, Ltd.

Submission Purpose Unconditional registration of a new chemical:
Resubmission with revised labeling

Type Formulation Liquid to be used as formulated

<u>Active Ingredient(s):</u>	<u>%</u>
Tributyltin maleate.....	25

200.0 Introduction

200.1 Use(s): See attached revised label and data sheet.

200.2 Background: See previous review by Efficacy Section (Disinfectants), EEEB, RD, dated 06-02-78.

200.3 Factors Affecting Amount/Type of Data Required: The proposed use is not related to human health. Therefore, efficacy data are waived.

TECHNICAL SUPPORT SECTION EFFICACY REVIEW - II

Disinfectants Branch

EPA Reg. No. or File Symbol 10466-EI
Date Division Received 03-06-80
Data Accession No(s). None
Product Manager No. 31 (Lee)
Product Name Steri-Septic DM-50
Company Name Thomson Research Associates, Ltd.

202.0 Recommendations

202.1 Claims Related to Human Health: No claims.

202.2 Claims Not Related to Human Health: Comparison of the bacteriostatic claims on the previous and current labels indicates the following:

- The claim for in-can bacteriostatic preservation of latex paint has been deleted. This is acceptable.
- The vague claim for bacteriostatic preservation of "water-based adhesives" has been retained and extended to include "the products to which such adhesives are applied such as canvas, footwear, and wallpaper". This is too broad, and is unacceptable.
- A bacteriostatic protection claim is now made for "vinyls used in products such as shower curtains". This is unacceptable.

203.0 Labeling

203.1 Revisions: Most of the microbiological problems alluded to on the current label are primarily, if not exclusively, fungal in origin. The only obvious bacterial deterioration problems would be expected in some kinds of water-based adhesives and emulsions. Therefore, in lieu of documentation of other bacteriological deterioration problems, the label should be revised as follows-

- Restrict the claims as a bacteriostatic preservative to defined types of water-based adhesives and emulsions where bacterial problems are known (e.g. gelatin, latex, or starch-based).

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- b. Provide clear and specific claims and directions for use of the product as a bacteriostatic preservative for the above substrates. The current data sheet is inadequate in this regard. In addition to the recommended dosage rate in terms of weight or volume of product and substrate, the directions for use must indicate how, when, and where the product is to be applied, as well as the intended nature (in-can, in-use, etc.) and duration (days, weeks, months) of preservation for each type (gelatin, latex, starch, etc.) of substrate claimed.
- c. The name "Steri-Septic" is misleading and unacceptable for this product since it does not provide sterilization. Qualification of a misleading coined name, i.e. "Steri-Septic Bacteriostat", is also no longer acceptable.